

JUN 18 2003

K023335

510 (K) SUMMARY

Submitter: Junqi Qian, M.D., President
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Date Summary Prepared: June 12, 2003

Device Name: Common Name: QCS control slides for HER2 immunohistochemistry.
Trade Name: *QCS HER2 ImmunoControls* (Product No. C010).

Device Classification: Class I or Class II has been proposed for immunohistochemical controls.

Panel: The proposed device classification is under the Hematology and Pathology devices panel. Division of Clinical Laboratory Devices.

Predicate Device: **Control slides** in DAKO HercepTest Kit (Product Code No. K5204, FDA PMA# P980018). DAKO HercepTest is a semi-quantitative immunohistochemical assay to determine HER2 overexpression in breast cancer. This kit includes primary antibody against HER2, secondary polymer, substrate and **control slides** prepared from cell lines.

Device Description: *QCS HER2 ImmunoControls*: This product provides appropriate control for semi-quantitative immunohistochemistry using polyclonal or monoclonal HER2/neu antibodies. Each slide contains four control sections prepared from breast cancer cell lines that represent different levels of Her-2/neu protein expression (-, 1+, 2+, 3+). These cells are formalin-fixed and paraffin-embedded, the slide is positively charged.

Intended Use: For *in Vitro* Diagnostic Use:
QCS HER2 ImmunoControls, are intended for laboratory use to control semi-quantitative immunohistochemistry using different Her2/neu antibodies. This control ensures that performance of immunohistochemical staining is consistent in one laboratory over time and also aids in correlation with the results of other laboratories.

Statement of substantial Equivalence:

Each QCS HER2 control slide contains four control sections prepared from breast cancer cell lines that represent different levels of Her-2/neu protein expression (-, 1+, 2+, 3+). These cells are formalin-fixed and paraffin-embedded, the slide is positively charged.

QCS HER2 controls are comparable in use and technology to DAKO HER2 control slides in HercepTest Kit, which is currently in commercial distribution. Similarities between the QCS HER2 controls and the DAKO HER2 controls include: 1) both products are prepared from formalin-fixed and paraffin-embedded human breast cancer cell lines; 2) both products can be stained by HER2 polyclonal and monoclonal antibodies using the same protocol; 3) both products can be used as controls for semi-quantitative immunohistochemistry; and 4) the scoring method of staining intensity is the same. The differences between the two products include: 1) Each QCS HER2 control slide contains 4 sections (-, 1+, 2+, 3+), while DAKO HER2 control slide contains 3 sections (-, 1+, 3+); 2) the cell lines in QCS controls (MDA-361, MDA-453 and MCF-7) are different from DAKO controls. Multiple studies demonstrate the following expected results as presented in Table 1.

Table 1. Immunohistochemical Characteristics of Cell Lines in QCS and DAKO HER2 Controls

Antibodies	QCS HER2 Controls				DAKO HER2 Controls		
	MDA-361	MDA-453	MDA-175	MCF-7	SK-BR-3 (3+)*	MDA-175 (1+)*	MDA23 1 (0)*
CB11 (Cell Marque)**	3+	2+	1+	-	3+	1+	-
HercepTest (DAKO)	3+	2+	1+	-	3+	1+	-

*Expected level of staining for valid results on the DAKO cell line control slide, as given in the HercepTest protocol (DAKO, Carpinteria, CA). All these 7 cell lines are human breast cancer cell lines.

**Representative HER2 ASR antibody.

Antigen stability testing indicates that QCS HER2 ImmunoControls are stable for at least 6 months once manufactured.

References:

- 1) Rhodes A, Jasani B, Couturier J, McKinley MJ, Morgan JM, Dodson AR, Navabi H, Miller KD, Balaton AJ. A formalin-fixed, paraffin-processed cell line standard for quality control of immunohistochemical assay of HER-2/neu expression in breast cancer. *Am J Clin Pathol.* 2002 Jan;117(1):81-9.
- 2) Taylor CR. The total test approach to standardization of immunohistochemistry. *Arch Pathol Lab Med.* 2000 Jul;124(7):945-51.
- 3) Ruby SG, McNally AC. Quality control of proliferation marker (MIB-1) in image analysis systems utilizing cell culture-based control materials. *Am J Clin Pathol.* 1996 Nov;106(5):634-9.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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President
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Re: k023335
Trade/Device Name: QCS ImmunoControl slides for HER2 Immunohistochemistry
(Product Code C010)
Regulation Number: 21 CFR § 864.1860
Regulation Name: Immunohistochemistry Reagents and Kits
Regulatory Class: II
Product Code: NJW
Dated: May 15, 2003
Received: May 16, 2003

Dear Dr. Qian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

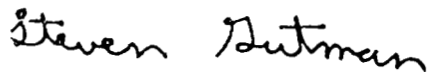
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 –

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.

Director

Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): K023335

Device Name: QCS ImmunoControl slides for HER2
Immunohistochemistry (Product Code C010)

Indication For Use:

For *in Vitro* Diagnostic Use:

QCS HER2 ImmunoControls, are intended for a laboratory to control semi-quantitative immunohistochemistry using different HER2/neu antibodies. Each QCS HER2 control slide contains four control sections prepared from breast cancer cell lines that represent different levels of Her-2/neu protein expression. The cells are formalin-fixed and paraffin-embedded. These controls ensure that performance of immunohistochemical staining is consistent in one laboratory over time and also aids in correlation with the results of other laboratories.

FDA/CDRH/ODE/STO
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephine B. Anttila
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K023335

OR

Over-The-Counter Use ____

Prescription Use ☒
(Per 21 CFR 801.109)

(Optional Format 1-2-96)